

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended). A multi-component pharmaceutical dosage form suitable for retaining and selectively releasing a drug substance which drug substance can be released to provide a controlled drug release profile in [[the]] a gastrointestinal environment, characterised by comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining at least one a first cavity said cavity having a first mouth opening; and

a first film means connected fixedly attached to the body first rim outside of the at least one cavity and closing the first mouth opening, wherein a thickness of the film is substantially thinner than a thickness of the first skirt wall and wherein the film is configured to be directly adjacent the first mouth opening.

2. (Currently amended). A multi-component pharmaceutical dosage form according to claim 1 wherein the body and/or the first film means is made of materials such that the dosage form opens to release the drug substance in the GI the gastro-intestinal environment.

3. (Currently amended). A multi-component pharmaceutical dosage form according to claim 1 wherein the first film means is connected fixedly attached to the body by a weld.

4. (Original). A multi-component pharmaceutical dosage form according to claim 3 wherein the weld is an ultrasonic weld.

5. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening;

according to claim 1 wherein the body comprises further includes a ledge formed on the first skirt wall between the base wall and the first rim, the dosage form further including a second film fixedly attached to the ledge inside of the first cavity a first cavity and a second cavity therein, the first and second cavities having a first and a second mouth opening respectively, and a first and second film means connected to the body and closing the first and second mouth openings.

6. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening

according to claim 5 wherein the body includes a second skirt wall axially extending in a second direction opposite the first direction from the base wall and terminating in a second rim, said body defining a comprises a base wall having an upper surface, the first cavity is defined by a skirt wall extending away from the upper surface of the said base wall to terminate in a rim defining the first mouth opening, the second cavity having a second mouth opening, the dosage form further including a second film fixedly attached to the second rim outside of the second cavity is defined by a skirt wall extending away from the lower surface of said base wall to terminate in a rim defining the second mouth opening.

7. (Currently amended). A multi-component pharmaceutical dosage form according to claim 6 wherein at least one of the first and/or second film ~~means~~ is a blister convex relative to the respective first and/or second mouth opening cavity.

8. (Currently amended). A multi-component pharmaceutical dosage form according to claim 6 wherein at least one of the first and/or second film ~~means~~ is substantially planar relative to the respective first and/or second mouth opening cavity.

9. (Currently amended). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first flexible film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening

according to claim 1 wherein the body includes a second skirt wall axially extending in the first direction from the base wall and terminating in a second rim, said body defining a comprises a base wall having an upper surface, both the first and second cavity having a cavities are defined by adjacent skirt walls extending from the upper surface of the said base wall to terminate in a rim defining the respective first and second mouth opening openings, the first and second film means connected fixedly attached to the body close both the first and second rims outside the first and second cavities, closing the first and second cavities mouth openings.

10. (Currently amended). A multi-component pharmaceutical dosage form according to claim 9 wherein the first and second cavities are adjacent and are divided from each other by a common skirt wall and the first and second rims of their mouth openings are substantially coplanar.

11. (Currently amended). A multi-component pharmaceutical dosage form according to claim 1 wherein the first film means comprises a first film layer and second film layer at least partially spaced apart from the first film means layer and defining a compartment suitable for retaining configured to retain a drug substance between said first and second film layers means.

12. (Currently amended). A multi-component pharmaceutical dosage form according to claim 11 wherein the body comprises a base wall and a skirt wall extending therefrom to terminate in a rim defining the mouth opening, the mouth opening being closed by a the first film means and a layer and the second film means layer are both fixedly attached to the first rim outside of the first cavity by a weld is located under the said first film means-

to define an upper compartment between the first film means and the second film means.

13. (Currently amended). A multi-component pharmaceutical dosage form according to claim 11 wherein the body comprises a base wall and a skirt wall extending therefrom to terminate in a rim defining the mouth opening, the first mouth opening being closed by a first film means and a second film means intermediate between the said first film means and the base wall to defines a first compartment between the first film means and the second film means and a second compartment between the second film means the second film layer is disposed between the first film layer and the base wall and the first film layer is convex relative to the first mouth opening.

14. (Cancelled).

15. (Currently amended). A dosage form according to claim 1 comprising a first cavity having wherein the body is a first body and the base wall is a first base wall, the dosage form further including a second body having a second base wall and a second skirt wall axially extending from said base wall and terminating in a second rim, said second body defining a second cavity having a second mouth opening, wherein the first and second a mouth opening and a second body comprising a second cavity having a mouth opening which bodies are connected to each other such that the second rim surrounds the first rim around respective rims of each mouth opening and [[a]] the first film means is disposed between and separates the first cavity from the second cavity.

16. (Currently amended). A dosage form according to claim 15 comprising a first wherein the second body which comprises is a first capsule shell defining a first cavity, having a first mouth opening and an opposite closed end,

a second and the first body comprises is configured as a closure for the first mouth opening, and the second body defines a second cavity having a second mouth opening the capsule shell such that the first and second mouth openings are facing toward one another the closed end of the first body when the second body is in place as a closure,

and the second mouth opening is closed by a film means, such that the film means is between the first and second cavities.

17. (Currently amended). A dosage form according to claim 16 wherein the second first body fits in a plug and socket relationship into the first second mouth opening via a plug and socket relationship.

18. (Currently amended). A dosage form according to claim 16 which further comprises a second comprising another capsule shell defining a further third cavity, having a further third mouth opening and an opposite closed end, and wherein the second first body is further configured as comprises a closure for this further the third mouth opening of this second capsule shell.

19. (Currently amended). A dosage form according to claim 18 wherein the second first body fits in a plug and socket relationship into the further third mouth opening via a in a plug and socket relationship.

20. (Cancelled).

21. (Currently amended). A dosage form according to claim 18 which comprises comprising a substantially linear arrangement of:

a first capsule shell defining a first cavity and having a first mouth opening,
a second body fitting in a plug and socket relationship into the first mouth opening via a plug and socket relationship, the second body having a second cavity therein having a second mouth opening which is closed by a film fixedly attached to the second mouth opening outside of the second cavity means, such that when the second body is [[so]] fitted into the first mouth opening the film means is disposed between the first and second cavities,

and a further second capsule shell defining a further third cavity and having a further third mouth opening into which the second body fits in plug and socket relationship.

22. (Currently amended). A dosage form according to claim 16 wherein [[a]] the capsule shell is made of an immediate release polymer.

23. (Currently amended). A dosage form according to claim 18 22 comprising two wherein the capsule shells are both made of immediate release polymer.

24. (Currently amended). A dosage form according to claim 16 wherein the first film means closing the second mouth opening comprises an immediate release polymer.

25. (Currently amended). A dosage form according to claim 18 wherein the first and further capsule shells and the first film means are immediate release polymers polymer,

and the first and second cavities enclose respective drug substances intended for immediate release.

26. (Currently amended). A dosage form according to claim 16 wherein ~~component parts of the dosage form~~ the first and second bodies are connected together by a weld.

27. (Cancelled).

28. (Currently amended). A dosage form according to claim 24 wherein the immediate-release film ~~means~~ comprises hydroxyethyl cellulose, low molecular weight hydroxypropylcellulose or low-substituted hydroxypropyl cellulose.

29. (Currently amended). A dosage form according to claim [[24]] 1 wherein the first film ~~means~~ is 20-300 micron thick.

30. (Previously presented). A dosage form according to claim 1 coated with a polymeric coating.

31. (Original). A dosage form according to claim 30 wherein the coating comprises a delayed or pulsed release polymer which dissolves or is otherwise breached in an environment of defined pH.

32. (Original). A dosage form according to claim 31 wherein said polymer is an enteric polymer.

33. (Cancelled).

34. (Currently amended). A dosage form according to claim 1 wherein the body comprises a delayed release polymer and the first film means comprises an immediate release polymer.
35. (Currently amended). A dosage form according to claim 5 wherein the first film means comprises an immediate release polymer and the second film means comprises a delayed release polymer.
36. (Cancelled).
37. (Currently amended). A body suitable for use in a pharmaceutical dosage form according to claim 1 comprising at least one base wall, a first wall extending from the base wall in a first direction and defining a first cavity having a mouth opening and adapted for connecting a polymer film thereto, and a second wall extending from the base wall in a second direction, opposite the first direction, and defining a second cavity having a mouth opening and adapted for connecting a polymer film thereto.
38. (Original). A body according to claim 37 comprising a delayed release polymer or an immediate release polymer.
39. (Original). A body according to claim 38 wherein the polymer comprises a delayed release polymer.
40. (Cancelled).
41. (Currently amended). A process for the preparation of a dosage form according to claim 6 1, optionally wherein the body comprises two cavities, comprising the following steps:

1. Forming [[a]] the body e.g. by injection moulding molding of a suitable polymer
 2. Optionally applying a polymer coat to the body.
 3. Filling [[a]] the first cavity with the drug substance
 4. Closing the first cavity with [[a]] the first film means
 5. Filling [[a]] the second cavity with the same or different drug substance
 6. Closing the second cavity.
42. (New). A multi-component dosage form according to claim 1, wherein the base wall includes a thinned region having a wall thickness less than the remainder of the base wall.
43. (New). A multi-component dosage form according to claim 1, wherein the body includes a second skirt wall axially extending in the first direction from the base wall and terminating in a second rim, said body defining a second cavity having a second mouth opening, the dosage form further comprising a second film fixedly attached to the second rim outside the second cavity.
44. (New). A multi-component dosage form according to claim 43 wherein the first film is made from an intermediate release polymer and wherein the second film is made from a polymer having a delayed release polymer.
- 45 (New). A multi-component dosage form according to claim 1 wherein the body is a first body that further includes a second skirt wall axially extending in the first direction from the base wall and terminating in a second rim, said body defining a second cavity having a second mouth opening, the dosage form further comprising:

a second body having a base wall and a skirt wall axially extending therefrom and terminating in a rim defining a second body cavity;

wherein the first and second bodies are connected to each other such that the rim of the second body surrounds the first and second rims of the first and second cavities of the first body; and

wherein the first film is disposed between the first cavity of the first body and the cavity of the second body.

46. (New). A multi-component form according to claim 1 wherein the first film is a laminate film comprising a plurality of separate layers.

47. (New). The multi-component pharmaceutical dosage form according to claim 1, wherein a ratio of the thickness of the skirt wall to the thickness of the film is greater than approximately 3 and less than approximately 20.

48. (New). The multi-component pharmaceutical dosage form according to claim 1, wherein a ratio of the thickness of the skirt wall to the thickness of the film is greater than approximately 2 and less than approximately 25.

49. (New). The multi-component pharmaceutical dosage form according to claim 1, wherein the film thickness is greater than approximately 20 microns and less than approximately 300 microns.

50. (New). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to and provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first laminate film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening.

51 (New). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first convex film fixedly attached to the first rim outside of the at least one cavity and closing the first mouth opening.

52. (New). A multi-component pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment, comprising:

a body having a base wall and a first skirt wall axially extending in a first direction from said base wall and terminating in a first rim, said body defining a first cavity having a first mouth opening; and

a first film fixedly attached to the first rim outside of the at least one cavity via a welded joint between the first film and the first rim, the first film closing the first mouth opening.